

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Leneau and Skelly
Serial No. : 09/586,510
Filing Date : June 2, 2000
Title : METHODS OF MAKING AND USING (Ig)
IMMUNOGLOBULIN COMPOSITIONS
Group/Art Unit : 1644
Examiner : R.B. Schwadron
Confirmation No. : 7522
Docket No. : 503775.008

DECLARATION II OF JAMES J. SHELDON

I, James J. Sheldon, do hereby declare and state as follows:

1. I have a Doctorate of Veterinary Medicine from Iowa State University (1961) and I am a Board Certified Veterinary Pathologist (Diplomate of the American College of Veterinary Pathology).
2. I have been employed in the veterinary animal health industry for over forty (40) years.
3. I have been employed as a Professor and Pathologist at the University of Arizona, College of Agriculture (1964 - 1972). I was a visiting professor, Department of Veterinary Pathology, College of Veterinary Medicine, Iowa State University (1970 - 1971) during a sabbatical. I was employed as a professor, Department of Veterinary Pathology, School of Veterinary Medicine, University of Missouri (1972 - 1973). Since 1973, I have been in private veterinary consulting and laboratory diagnostic support to the cattle industry in the southwestern United States.
4. I have specialized in bovine respiratory disease complex, its prevention and control in the cattle industry. I have acted as the principal investigator and supervisor of a considerable amount of research during the past forty (40) years.

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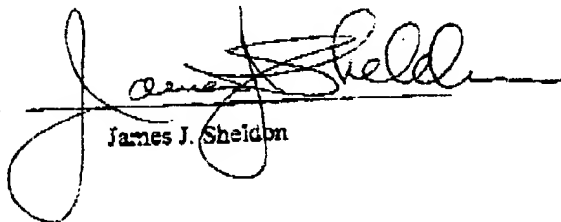
5. I have reviewed and am familiar with the subject matter disclosed in the above referenced patent application.
6. William G. Skelly, one of the inventors of the above referenced patent application, disclosed to me the concept of using immunoglobulins (Ig) to treat stress induced respiratory disorders. After such disclosure, I began to research the use of Ig for a variety of disorders in cattle. I have documented evidence that the administration of Ig compositions can be used as an effective prophylactic treatment for "stress induced respiratory disorders" in cattle.
7. Under my direction and control, the Ig composition described in the background section of the above referenced patent application was used to treat stress induced bovine respiratory disorders in a commercial feedyard of calves. Dosages and routes of administration included single and booster injections of 15 - 60cc subcutaneously, and 250cc orally.
8. Empirical evidence of the reduction of stress induced respiratory disorders after immunization and metaphylaxis treatment of approximately 60% of a group of small, high risk feeder calves with the Ig composition showed a 38.6% reduction in morbidity compared to the control portion of calves which did not receive the Ig composition.
9. Under my direction and control, the Ig composition described in the background section of the above referenced patent application was used in an organic beef program involving calves from the Beef Master Ranches. Of those calves that required treatment for respiratory disease, the response to treatment with the Ig composition in combination with other therapies was 34% which is a substantial improvement over those calves which did not receive Ig composition.
10. This evidence establishes that the administration of Ig is an effective prophylactic treatment for stress induced respiratory disorders in cattle.
11. In view of the successful use of Ig for treating stress induced respiratory disorders in cattle, I believe that Ig would be useful in treating stress induced respiratory disorders in other animals.

12. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application and any issued patent resulting therefrom.

Date

05/7/02

James J. Sheldon





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TECH CENTER 1600/2900

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DECLARATION OF WILLIAM G. SKELLY

I, William G. Skelly, declare as follows:

1. I am a co-inventor of the subject matter of the above-identified patent application.
2. I am president of Central Biomedica, Inc., assignee of the above-identified patent application. Sera, Inc. is a wholly owned subsidiary of Central Biomedica, Inc. Sera, Inc. sells Ig compositions under the trademark SERAMUNE (R).
3. I have reviewed the article entitled "Passive Immunotherapy of Equine Respiratory Disease: Treatment of Acutely Ill Horses with Equine Immunoglobulins," The Equine Athlete, Vol. 8, No. 6 (1995), authored by Ragland, McCullough and Wilkey.
4. The authors of the above-reference article derived their knowledge of the invention disclosed and claimed in the above-identified patent application from me. Specifically, Leneau, other Central Biomedica, Inc. employees, and/or myself disclosed to the authors of the above-referenced article the concept of using Ig compositions for treating stress induced respiratory disorders, including respiratory diseases of horses. After such disclosure, the authors conducted the experiments described in the article, at our request, using standard techniques. In fact, Sera, Inc. provided the material used in the experiments described in the publication (see page 2, col. 1).
5. I confirm that the co-authors of the publication are not co-inventors of the subject matter of the above identified invention.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Date: October 8, 2002 By: W. G. Skely



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DECLARATION I OF HOWARD ERICKSON

I. Howard Erickson, do hereby declare and state as follows:

1. I have a Doctorate of Veterinary Medicine from Kansas State University (1959) and a Ph.D. degree from Iowa State University (1966) in veterinary physiology with minors in biomedical engineering and biochemistry.
2. I am a Professor of Physiology at the Kansas State University College of Veterinary Medicine, where I have been employed as a Professor of Physiology in the Department of Anatomy & Physiology since 1981. In 2001 I was named the Roy Walter Upham Professor of Veterinary Medicine.
3. In 1987 I spent a sabbatical leave at the Equine Research Station, Animal Health Trust, Newmarket, England and the College of Veterinary Medicine, Swedish University of Agricultural Sciences, Uppsala, Sweden.
4. I have received numerous honors and achievements in my field, including the Bayer Excellence in Equine Research Award (2000). I became a member of the Phi Zeta Honor Society of Veterinary Medicine in 1966. I was elected a Fellow of the American Association for the Advancement of Science in 1976 and a member of Phi Kappa Phi in 1985 which recognizes superior scholarship in all academic disciplines.
5. I have worked in the field of Equine Sports Medicine and Exercise Physiology since 1982. I have specialized in Exercise-Induced Pulmonary Hemorrhage

(EIPH), comparative exercise physiology, and cardiopulmonary physiology. I began to study exercise physiology in 1966 at the United States Air Force School of Aerospace Medicine.

6. Based upon my experience, I am very familiar with the terminology utilized in the fields of comparative exercise physiology, cardiopulmonary physiology and veterinary animal health.
7. I have reviewed and am familiar with the subject matter disclosed in the above referenced patent application.
8. It is well known in the veterinary animal health industry that the term "stress induced respiratory disorders" has the following meaning:
 - Steadily decreasing lung capacity brought on by "stress induced" elements.
9. It is well known in the veterinary animal health industry that "stress induced respiratory disorders" does not usually encompass any respiratory disorder that is caused by infectious or pathogenic agents. Specifically, it is well known to the bovine veterinary health industry that "stress induced" in the term "stress induced respiratory disorder" is interpreted to exclude pathogenic disorders. Furthermore, the term "stress induced" is interpreted as encompassing, by way of example and not limitation, the following factors:
 - Elements outside the animal such as
 - The interaction with other animals
 - Temperature extremes
 - Transportation stress
 - Airborne irritants such as dirt, sand, hay, dust
 - Exercise
10. It is well known to the equine veterinary health industry that the term "stress induced respiratory disorders" and, therefore, "stress induced" factors as listed above specifically would encompass, by way of example and not limitation, the following:
 - Exercise-induced pulmonary hemorrhage
 - "Shipping Fever" or "Pleuropneumonia" associated with transportation

-Temperature extremes

-Airborne irritants such as dirt, dust, or moldy hay

11. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application and any issued patent resulting therefrom.

7 Oct 2002
Date

Howard H. Erickson
Howard H. Erickson, DVM, PhD

Professor of Physiology and
Roy W. Upham Professor of Veterinary Medicine
College of Veterinary Medicine
Kansas State University
Manhattan, KS 66506